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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,646	09/18/2001	Seth A. Foerster	END-777	8823

34263 7590 06/30/2005

O'MELVENY & MEYERS  
114 PACIFICA, SUITE 100  
IRVINE, CA 92618

EXAMINER
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MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/954,646

Applicant(s)

FOERSTER ET AL.

Examiner

Eleni Mantis Mercader

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46-51, 54-62 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-51, 56, 57, 60, 62 and 67 is/are rejected.
- 7) ☒ Claim(s) 54, 55, 58, 59, 65 and 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/15/05
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 46-51, 56-57, 60, 62 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al.'936 of record in view of Kandany'613 (US Patent No. 5,562,613).

Campbell et al.'936 teach an introducer for inserting a marker element into a particular tissue element having an introducer with a tube having a lumen an axial opening at the proximal end of the tube (see in Figure 10, plunger 18), a side exit port at the distal end of the port (see Figure 15 below, element 22) with at least one discrete marker positioned in the tube (see Figure 18 showing a marker cartridge assembly for delivering markers at the area of interest) and a shaft extending from the axial opening and ejecting the marker from the side exit port by the application of compressive force (referring to the plunger 18 pushing the marker 30; see col. 4, lines 24-58) such that no marker element extends outside the body (referring to subcutaneous penetration; see col. 1, lines 33-43).

Campbell et al.'936 do not teach a closed distal end and a side exit port defining a plane, the plane being parallel to the longitudinal axis of the tube, wherein the side exit port is located adjacent a distal end of said tube.

In the same field of endeavor, Kaldany'613 teaches a closed distal end and a side exit port defining a plane, the plane being parallel to the longitudinal axis of the tube, wherein the side exit port is located adjacent a distal end of said tube for the introduction of pellets of interest (see Figure 7 and respective specification description in col. 5, lines 22-34).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Campbell et al.'936 and incorporated the teaching of Kaldany'613 in order to alter the end of the catheter to have a closed distal end with a side exit port defining a plane, the plane being parallel to the longitudinal axis of the tube, wherein the side exit port is located adjacent a distal end of said tube in order to enable the physician to advance the marker at the area of interest with greater precision once the side port has been aligned with the tissue of interest by allowing for a simple unidirectional handed motion (see for motivation to combine Kaldany'613, col. 2, lines 45-49).

Campbell et al.'936 further teaches a plurality of markers capable of being introduced (see col. 7, line 65- col. 8, line 16).

The use of expandable markers to further enhance attachment to the tissue of interest while allowing for easier transfer through the lumen and the variety of materials used for such markers as long as they are biocompatible are well known functional equivalents to skilled artisans.

***Allowable Subject Matter***

3. Claims 54-55, 58-59, 61, 65-66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Conclusion*

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Barsch'177 teaches an apparatus and method for deploying an expandable biopsy marker.

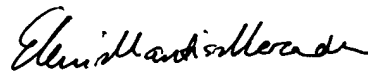
Simon'329 teaches an adjustable localization device.

Burney et al.'700 teaches a biopsy marker assembly.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM